



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Dox 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	1	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/914,795		09/05/2001	Gunther Berndl	49727	4232	
26474	7590	09/10/2003				
KEIL & WEINKAUF				EXAMINER		
1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036				GOLLAMUDI,	GOLLAMUDI, SHARMILA S	
				ART UNIT	PAPER NUMBER	
				1616	10-	
				DATE MAILED: 09/10/2003	/8	

Please find below and/or attached an Office communication concerning this application or proceeding.

200	Applicati n No.	Applicant(s)					
	09/914,795	BERNDL ET AL.					
Advisory Action	Examiner	Art Unit					
	Sharmila S. Gollamudi	1616					
The MAILING DATE f this communicati n appe	ears on the c v r sheet with the	correspondence address					
THE REPLY FILED 27 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.							
PERIOD FOR REPLY [check either a) or b)]							
a) The period for reply expires 3 months from the mailing date of the final rejection. The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.							
2. The proposed amendment(s) will not be entered because:							
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);							
(b) They raise the issue of new matter (see Note below);							
(c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or							
(d) they present additional claims without canceling a corresponding number of finally rejected claims. NOTE:							
3 Applicant's reply has overcome the following rejection(s):							
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).							
5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for application in condition for allowance because: s	or reconsideration has been con ee continuation sheet.	sidered but does NOT place the					
The affidavit or exhibit will NOT be considered be raised by the Examiner in the final rejection.	cause it is not directed SOLELY	to issues which were newly					
7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims with the proposed amendment of the proposed amendment	nt(s) a)⊡ will not be entered or would be rejected is provided be	b)∏ will be entered and an elow or appended.					
The status of the claim(s) is (or will be) as follows							
Claim(s) allowed:							
Claim(s) objected to:							
Claim(s) rejected:							
Claim(s) withdrawn from consideration:							
8. The proposed drawing correction filed on is a) approved or b) disapproved by the Examiner.							
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s)							
10. Other:							

Application/Control Number: 09/914,795

Art Unit: 1616

Applicant argues that Baert does not teach or suggest each element of the present claims. It is argued that the reference does not teach the instant binders. Furthermore, the applicant argues that Baert only introduces the binders after the melt-extrusion process.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to column 3, lines 33-40 wherein the Baert teaches the use of thermoplastic or thermomelting polymers. These polymers are combined with cyclodextrin and active agents and then melted. Additionally column 4, lines 15-25 is pointed out wherein the process includes mixing the cyclodextrin and active agent, optionally mixing in additives, followed by melting the mixture. Clearly the polymer is added before the melting process to ensure mixing of all ingredients. The crospovidine the applicant speaks of, is utilized for the preparation of the solid dosage form. As seen from the examples, the melt-extrudate is used to make the dosage form.

Secondly, the examiner points out that the claims are rejected under an obviousness rejection; therefore Baert does not have to disclose each and every element of the instant. As clearly stated in the office action dated June 12, 2003, Baert only lack in its teaching of the specific polymers. Thus, Kilmesh et al is relied upon to teach the instant polymer. Kilmesh teaches the method of tabletting extrudable composition. Further, Kilmesh teaches the instant melt-extrusion polymers are used conventionally to make the active agent in to a paste form. It is clear these polymers are added to form the melt-extrudable composition. Thus, one would be motivated to combine Baert et al and Kilmesh et al and utilize the instant polymers since Kilmesh

teaches that the instant polymers are conventionally used in the art for melt-extrudable composition. One would expect similar results since Baert utilizes melt-extrusion, which is a polymer extrusion technique that involves utilizing thermomelting polymers.

The rejection of Baert in view of Shultz is removed after further reconsideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG hand Soff

THURMAN K, PAGÉ, J.D. SUPERVISORY PATENT EXAMINER